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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Serial Number: 08/071,052
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Appellant(s): JEFFERY W. KREAMER

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95-4911
Davis, Hockenberg, Wine, Brown, Koehn & Shors
For Appellant

EXAMINER'S ANSWER

BOARD OF PATENT APPEALS
AND INTERFERENCES

This is in response to appellant's brief on appeal filed
January 18, 1995.

(1) *Status of claims.*

The statement of the status of claims contained in the brief
is correct.

(2) *Status of Amendments After Final.*

The appellant's statement of the status of amendments after
final rejection contained in the brief is correct.

(3) *Summary of invention.*

The summary of invention contained in the brief is correct.

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(4) *Issues.*

The appellant's statement of the issues in the brief is correct.

(5) *Grouping of claims.*

The brief includes a statement that claims do not stand or fall together but fails to present reasons in support thereof. Therefore, these claims are presumed to stand or fall together.

(6) *Claims appealed.*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(7) *Prior Art of record.*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

4,088,778	Igarashi et al.	May 9, 1978
4,874,603	Fratzer	October 17, 1989
4,970,081	Frisbee	November 13, 1990

(8) *New prior art.*

No new prior art has been applied in this examiner's answer.

(9) *Grounds of rejection.*

The following ground(s) of rejection are applicable to the appealed claims.

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The specification is again objected to under 35 U.S.C. § 112, first paragraph, as the proportions of active agents present in the synergistic compositions are not clearly set forth in the specification. The dose ranges on page 13 do not set forth what ratios of active agents will yield the desired synergistic effect. The applicant argues that the amounts would be obvious to the skilled artisan. However, applicant is claiming a synergistic effect which is not clearly demonstrated on the record. The active agents individually are admitted to possess the characteristics claimed. There is no clear teaching of the proportions needed to effect the synergistic activity.

Claims 11-26 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 11-26 fail to recite the active agents or the ratio of active agents which will yield the synergistic effect. The declaration indicates that a combination of Vitamins and minerals are used and not a single vitamin or mineral as claimed in 13-23.

The claims are not commensurate with the scope of the data which applicant argues shows a synergistic activity. The data does not teach that each of the medicaments claimed in claims 11-26 are effectively individually or in a prescribed combination.

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Claims 11-26 are rejected under 35 U.S.C. § 103 as being unpatentable over Igarashi et al (778), Fratzer (603) and Frisbee (081). Igarashi and Fratzer each teach in their abstracts the use of Vitamin E to treat a vascular disease and Frisbee discloses at column 1, lines 25 to 30 that aspirin can be used to treat vascular diseases.

It is deemed well settled patent law that the combination of ingredients of known character where the results obtained are no more than additive of the individual character will not be patentable. It is clear from applicants admissions that each of the claim designated ingredients are known to have beneficial results in patients. The use of the two ingredients or three in a single combination would have been obvious to those skilled in the art given the known characteristics of each component.

The declaration of Dr. Larry H. Hollier has been carefully reviewed but is not deemed persuasive. The copy of the graphs provided the examiner do not show a distinction between the bars. As there is no clear explanation as to their relationship it appears that the bars show an additive effect rather than a synergistic effect.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is

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to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-277, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

In this application it would have been prima facie obvious to administer aspirin and a multiple vitamin conjointly to treat heart conditions. The effects claimed in claims 11-16 on the prostaglandin function in platelets and migration of cholesterol would be inherent in the individual administration of the claimed active agents.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

(10) *New ground of rejection.*

This Examiner's Answer does not contain any new ground of rejection.

(11) *Response to argument.*

Appellant argues that the skilled artisan would know which amounts of active agents to utilize since the amounts of vitamins

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and aspirin are well recognized in the art and are available in commercial products.

Appellants' specification is objected to as there is no clear teaching in the specification that the combination of aspirin and a claimed vitamin synergistically reduces arteriosclerotic plaque with the effect reducing deaths due to heart disorders. Examples of the lack of clarity in the specification are:

1. Appellant at page 15 of the specification states that aspirin alone administered once a week showed the greatest relative risk reduction. Previously, at page 4 one aspect of the appellant's invention is that aspirin and a vitamin alone or in combination increases the therapeutic effect on vascular disease. and

- 2, The appellant relies on the results of the University of California study to establish synergism. However, appellants's invention is purported to refute the detrimental effects of this study. See page 4 of appellant's brief. It is unclear to the examiner what is established by the data set forth therein.

In view of the confusion and ambiguous statements in the specification and brief it is deemed that the objection to the specification and rejection under 35 U.S.C. 112, first paragraph, is proper.

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Appellant argues that the University of California data establishes that combining aspirin and vitamin would decrease the risk of death. However, there is no data to illustrate that an individual vitamin or mineral as claimed would have such an effect.

The data submitted can not be clearly evaluated by the Examiner since there is no comparative data relative the claims for t synergistic effect.

The rejection under 35 U.S.C. 103 is deemed proper since a clear synergistic activity having statistical significance has not been demonstrated and the claims are not within the scope enabled by the specification.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



T.J. Criares
Examiner
Art Unit 1205
April 10, 1995

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